IN THE UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA, CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WISCONSIN *Ex rel.* CATHLEEN FORNEY Plaintiffs, vs. MEDTRONIC, INC., Defendant.	Case No. 5:15-cv-6264-EGS ORAL ARGUMENT REQUESTED

DEFENDANT'S STATEMENT OF UNDISPUTED FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

Burns Complaint

1. On August 19, 2011, the United States District Court for the Middle District of Florida unsealed the complaint and all other papers filed in the matter captioned *United States of America ex rel. John Burns v. Medtronic, Inc. et al.*, Case No. 8:10-cv-1851. (Ex. A, Burns Unsealing Order).

2. The Burns Complaint alleged that "[p]atients with implanted pacemakers and defibrillators to regulate their heart rhythm need their pacemakers and defibrillators rechecked approximately every three months." (Ex. B, Burns Compl. ¶ 19).

3. Burns alleged that he personally had performed these device checks for patients with Medtronic's implanted pacemakers and defibrillators "[s]ince he started working at Medtronic in 2000." (Ex B., Burns Compl. ¶ 27).

4. According to Burns, Medtronic did not bill Medicare for the hundreds of device checks performed by each of its sales representatives yearly. (Ex. B, Burns Compl. at ¶ 28). Instead, "Medtronic has routinely allowed cardiologists who implant Medtronic pacemakers and defibrillators to have those devices rechecked for free and has routinely enabled those cardiologists to fraudulently bill Medicare under global procedure codes so that they could be paid by Medicare for performing . . . work which they had not done." (*Id.*).

5. Burns alleged that in this manner, Medtronic "caused physicians to submit false and fraudulent claims to Medicare for the technical component of pacemaker and defibrillator equipment checks which the physicians did not perform." (Ex. B, Burns Compl. ¶ 26).

6. In addition to alleging company-wide misconduct at Medtronic, Burns identified specific physicians whom he alleged submitted false claims, and he identified the specific districts and states in which he claimed to have personally witnessed this misconduct. (Ex. B., Burns Compl. ¶¶ 29-30).

7. The Burns complaint alleged that the practice of providing free device checks began years ago and continued to the present, stating that "Medtronic[] has been doing free pacemaker rechecks and enabling cardiologists to fraudulently bill Medicare for that work for at least the past ten years John Burns has worked for Medtronic[]." (Ex. B, Burns Compl. at ¶ 30).

8. Regarding Medtronic's intent, Burns alleged that he and his colleagues understood that the purpose of providing free device checks was to induce sales of Medtronic's cardiac rhythm products. (Ex. B, Burns Compl. ¶¶ 36-38).

9. In further support of his claim that Medtronic knew or should have known that providing free device checks was impermissible, Burns cited to the July 2009 AdvaMed Code of Ethics, which reads in part, "[A] Company should not provide free services that eliminate an overhead or other expense that a Health Care Professional would otherwise of business prudence or necessity have incurred as part of its business operations if doing so would amount to an unlawful inducement." (Burns Compl. at ¶ 24). The Burns Complaint also referenced a handbook regarding the AdvaMed Code titled *Deciphering the Code: A guide to the shared principles, policies and practices governing the CRM industry*, which was distributed by Medtronic, Boston Scientific, St. Jude Medical, Sorin Group, and Biotronik. (Burns Compl. Ex. 4, PageID 22).

10. While the Burns matter remained under seal, the United States advised the court that it was conducting an investigation; analyzing claims data; and scheduling interviews with former Medtronic employees. (Ex. C. Memo in Support of Motion to Extend Burns Seal, at 2-3).

Onwezen Complaint

11. On December 2, 2011, the United States District Court for the District of Minnesota unsealed a *qui tam* complaint filed by Kathy Onwezen and two co-relators against Medtronic. (Ex. D, Onwezen Unsealing Order).

12. The Onwezen complaint alleged that Medtronic provided various forms of remuneration in contravention of the Anti-Kickback Statute, including "invitations to exclusive parties, tickets to sport events, and the use of expensive 'loaner' equipment for indefinite periods of time." (Ex. E, Onwezen Compl. ¶ 7). But the complaint alleged that device checks and other post-implant services for cardiac rhythm devices were the most significant issue:

> But by far the most egregious form of remuneration provided by Medtronic is its promise to doctors and physicians that it will provide *substantially all device-related post-implant*

> *medical care* to any patient who has received a Medtronic device. In the majority of cases, once a patient receives a Medtronic cardiac rhythm device, Medtronic becomes a "one-stop-shop," through which the Company, and not the doctor, conducts *nearly all follow-up "medical"* care related to the device for that patient. Medtronic uses unlicensed and/or non-medical staff, such as Sales Representatives and Clinicians, to conduct virtually all follow-up consultations with the patient, answer any patient inquiries, make adjustments to the device, and recommend any additional follow-ups.

(Ex E., Onwezen Compl. ¶ 8).

13. The relators alleged that Medtronic used these technical support practices to induce sales, telling doctors and hospitals that Medtronic representatives would perform all of the necessary post-implant follow-up tasks:

> As part of its efforts to corner the market, Defendant promises both doctors and hospitals that use Medtronic's cardiac rhythm devices that it will provide all follow-up care for those patients. Physicians often complain that checking the devices during their clinic times is time-consuming and expensive. As an incentive for doctors and hospitals to choose Medtronic devices, Medtronic Representatives tell doctors and hospitals that if they use a Medtronic device, they will not have to be involved in any of the patient's follow-up care. Instead, Medtronic will send a Representative to the doctor's office or clinic to see the patients, advise the patients on any necessary follow-up care, make adjustments to the implanted device, and even make house calls for the doctor, without a licensed physician or staff member present.

(Ex. E, Onwezen Compl. ¶ 68).

14. According to the Onwezen complaint, the post-implant product support offered by Medtronic was so extensive that (1) it was "not unusual for a Medtronic Representative to see up to forty patients a day" (Ex. E, Onwezen Compl. ¶ 69); (2) the implant procedure was "often the first and last time the implant patient will ever see the doctor," because a Medtronic representative would handle all other follow-up work, (*id.*, ¶ 70); (3) Medtronic wanted its representatives to have "virtually total autonomy over post-surgical patient care," (*id.*, ¶ 71; *see also id.*, ¶ 77); and (4) Medtronic representatives would interact with patients over the phone, at doctors' offices, at patients' homes, and in nursing homes, (*id.*, ¶¶ 72-74).

15. The relators in Onwezen also alleged that it was common for Medtronic field personnel to provide product support during the surgical procedures in which pacemakers and defibrillators were implanted:

> It is common practice for a Sales Representative, Clinician or other knowledgeable representative of the manufacturer of the device ("Representative") to be present throughout the procedure to answer any questions that may arise about the device, provide guidance about installation and program the device (or "run the equipment"). Running the equipment requires conducting an "interrogation" of the device, performing device systems checks and programming the patient's identifying data onto a telemetric (or programming) wand.

(Ex. E, Onwezen Compl. ¶ 54).

16. As an additional component of the alleged scheme, the Onwezen relators alleged that Medtronic personnel handled all aspects of the remote monitoring and billing processes for customers, and completed "all of the paper-work related to billing for implant patients." (Ex. E, Onwezen Compl. ¶¶ 78-82, 95-104). Regarding the implant paperwork, the relators alleged that the Medtronic representative who attended and assisted the implant procedure would prepare an "'Implant Data Report,' which identifies the specific device . . . implanted, along with all serial numbers, programming data, the name of the physician who performed the procedure, and the name of the device company Representative who was present during the procedure." (*Id.* at ¶ 55). The Medtronic representative would also allegedly prepare a "detailed analysis of the entire implant procedure." (*Id.*)

17. The relators further alleged that Medtronic's field representatives provided reimbursement advice to physicians. Medtronic employees were allegedly "trained to sit down with the doctor and show him how s/he is under-billing. They are instructed to point out to doctors that, in order to maximize profits, they should turn over all billing responsibilities to a

Medtronic Representative." (Ex. E, Onwezen Compl., ¶ 75). Sales representatives would then allegedly review doctors' files and tell them how to bill for procedures. (*Id.* ¶¶ 87-88).

18. The relators alleged that this company-wide scheme had been ongoing since at least 1995, continued up through the present, and would continue into the future as patients continually needed their devices checked. (Ex. E, Onwezen Compl. ¶¶ 3, 76).

19. As supposed evidence of Medtronic's unlawful intent, the Onwezen complaint cited the corporate integrity agreement stemming from Medtronic's July 2006 settlement with the Department of Justice. (Ex. E, Onwezen Compl. ¶ 6).

Stokes Complaint

20. On October 25, 2013, the United States District Court for the District of Columbia unsealed a *qui tam* complaint filed by Ben Stokes against Medtronic, Boston Scientific, and St. Jude Medical. (Ex. F, Stokes Unsealing Order).

21. The Stokes complaint alleged that Medtronic, Boston Scientific, and St. Jude Medical provided post-implant technical support in such a way that they prematurely drained the batteries of their cardiac rhythm devices. (Ex. G, Stokes Compl. ¶ 4).

22. Stokes described the post-implant product support allegedly provided by Medtronic and its competitors in detail:

> After implantation, pacemakers require monitoring to ensure proper function and programming. The first device evaluation typically occurs within 4 months after implantation and continues throughout the life of the patient. It is at this first device monitoring appointment that the settings should be restored to the pacing threshold rates, so that the patient receives the nominal amount of energy needed to initiate a heartbeat and/or receive optimal therapy.

(Ex. G, Stokes Compl. ¶ 53)

> Unlike most other aspects of patient care in medicine, during implantation and throughout the follow-up care of the patient, representatives of the Defendant device manufacturers have direct contact with patients and typically handle device settings and function (aka "interrogation") and reprogram device settings (aka "reprogramming")

> through computerized evaluation of the device and radiofrequency communications with the device during follow-up. The "interrogation" and "reprogramming" typically take place in outpatient cardiologist practices or in outpatient hospital "device clinics." In either setting there are manufacturer personnel who are specifically trained to program the device settings, including energy output.

(Ex. G, Stokes Compl. ¶ 56)

23. Stokes claimed that these "device interrogations and reprogramming are customarily performed by the device representatives themselves, without direct physician supervision or review." (Ex. G, Stokes Compl. at ¶ 63).

24. According to Stokes, Medtronic and its competitors "have extensive programs in place to train their employed allied professionals in programming pacemaker settings." (Ex. G, Stokes Compl. ¶ 15). Stokes elaborated that the training requirements for manufacturer representatives who provide product support were established by the North American Society of Pacing and Electrophysiology, which published "Standards of Professional Practice for the Allied Professional in Pacing and Electrophysiology. PACE, Volume 26, pp. 127-131 (January 2003)". (Ex. G, Stokes Compl. p. 9, n. 1).

25. Stokes also claimed that he personally provided reimbursement advice across the country:

> In his role as Sr. Manager of Healthcare Economics employed by Defendant Medtronic, Mr. Stokes had the unique opportunity to travel throughout the United States, visiting hospitals and delivering education pertaining to documentation, coding and billing for cardiac devices such as pacemakers and ICDs. During his tenure of employment at Medtronic, he personally visited and worked with over 300 hospitals across 40 states. As he would visit with customers in the various facilities, they would share how their device costs, case mix, payor mix and utilization trends were impacting their overall profitability for these procedures.

(Ex. G, Stokes Compl. ¶ 59)

Schroeder Complaint

26. On May 27, 2014, the United States District Court for the Eastern District of California unsealed a complaint filed against Medtronic by Adolfo Schroeder. (Ex. H, Schroeder Unsealing Order).

27. Schroeder provided an overview of the cardiac rhythm devices that Medtronic manufactures:

> Devices manufactured and marketed by Medtronic include the Concerto CRT-D (cardiac resynchronization therapy and defibrillator) and Virtuoso DR ICD (implantable cardioverter defibrillator); the InSync Sentry CRT-D, the OptiVol fluid status monitoring device; CardioSight and Cardiac Compass cardiac monitoring devices; Reveal insertable loop recorder; sprint-fidelis lead system and other lead systems; cardiac compass monitoring device; carelink monitoring wireless at home system; and any additional ICD, CRT, pacemaker, fluid monitoring, cardiac monitoring devices, processes and lead systems sold by Medtronic from 2002 to present.

(Ex. I, Schroeder Compl. at ¶ 16).

28. Schroeder alleged that Medtronic differentiated itself from its competitors through kickbacks to physicians, since its cardiac rhythm devices "were not superior to other similar devices made by other companies on the market." (Ex. I, Schroeder Compl. ¶ 7).

29. Schroeder alleged Medtronic used reimbursement advice as an in-kind kickback:

> Medtronic also directed sales representatives to educate physician staffs on how to bill Medicare, Medicaid and other insurers, in effect offering unpaid work from Medtronic employees to doctor's offices. The sole purpose of this action was to increase the sales of Medtronic devices through the Medicaid, Medicare and private insurance systems.

(Ex. I, Schroeder Compl. ¶ 51).

30. According to Schroeder, reimbursement advice was incorporated into targeted meetings with physicians in an attempt to increase sales.

> In the February, 2005 Medtronic "Q3-Q4 AMP Business Plan," the 19 Medtronic sales staff planned to show Dr. Promad Multani how to "Break the bank." The Medtronic representatives planned to meet with him to "Emphasize realistic patient and econ[omic] numbers" he could realize from referrals for Medtronic implants, and to "Show DRG payments for Downey and St. Francis" - show him how other facilities were maximizing their billings. As a result, Dr. Multani was expected to deliver an ROI of two Medtronic implant referrals in the 3rd quarter, and 3 Medtronic implant referrals in the 4th quarter.

(Ex. I, Schroeder Compl. ¶ 74).

> Part of a Medtronic July 20, 2004 business plan was to select doctors who refer potential implant patients to the top volume implanters and educate them on the 'Economics of devices', and 'Reimbursements for devices' in order to show them how to maximize reimbursements and grow their clinic income.

(Ex. I, Schroeder Compl. ¶ 75).

31. Schroeder also alleged that Medtronic developed written materials that conveyed reimbursement and business advice, such as a "guide" that Medtronic allegedly gave doctors to help them better manage and receive reimbursement for heart failure clinics:

> For example, a January, 2006 Medtronic guide to help doctors build 13 "an Effective Heart Failure Clinic" provided 43 pages of instructions on which 14 ICD-9 codes to use when billing for a CRT or ICD implant. The guide also gave 15 suggestions on additional codes to use in order to maximize billings when 16 implanting devices.

(Ex. I, Schroeder Compl. ¶ 73).

32. As another example of mixed reimbursement and business consulting advice, Schroeder described a "turn-key" heart failure clinic program that Medtronic allegedly promoted:

> A February 20, 2007 Medtronic template letter to referral physicians stresses that their patient "has been identified as being potentially at high risk for sudden cardiac death, and may benefit from placement of an implantable cardioverter defibrillator and/or cardiac resynchronization therapy." The letter was part of a "turn-key" heart failure clinic business solution that Medtronic promoted to cardiologists and hospitals. Sales representatives were trained to show cardiologists how the physicians could use Medtronic pre-printed medical forms and templates to run a heart failure clinic, and to show them how much profit the physicians could make off Medicaid, Medicare and other payers if the physicians implanted Medtronic CRDM devices.

(Ex. I, Schroeder Complaint ¶ 81).

Doe Complaint

33. On June 20, 2016, the United States District Court for the District of New Jersey unsealed a *qui tam* a complaint filed by two anonymous relators. (Ex. J, Doe Unsealing Order).

34. The Doe complaint alleged a "nationwide, fraudulent scheme" by Medtronic and its competitors to "provide doctors with free technical services in connection with the necessary health monitoring of cardiac patients" with implanted cardiac rhythm devices "in exchange for their commitment to recommend use of their products and continued business." (Ex. K, Doe Compl. ¶ 3).

35. The anonymous relators described the post-implant device interrogation process in detail (Ex. K, Doe Compl. ¶¶ 70 73), noting that "[d]evice interrogations are typically done by an employee of the device manufacturer alongside a patient's cardiologist," (*id.*, ¶ 74).

36. The relators further explained that patients typically require "two (2) to four (4) interrogations per year," (Ex. K, Doe Compl. ¶ 75).

37. According to the Doe complaint, "[i]t is rare that a physician will conduct the technical component of the device interrogation due to certain complexities the device industry has created including operating the proprietary, highly complicated equipment needed to do the interrogation and more importantly, being unable to purchase the equipment for themselves." (Ex. K, Doe Compl. ¶ 76). "Instead, these services are provided by the Defendants gratis to doctors, such as Relators." (*Id.* ¶ 77).

38. The Doe complaint alleged that representatives from Medtronic and its competitors would typically perform device interrogations, regardless of whether a doctor or hospital had the necessary equipment on site. (Ex. K, Doe Compl. ¶¶ 81-83).

39. The Doe complaint also alleged specific instances in which representatives from Medtronic provided reimbursement advice to physicians. (Ex. K, Doe Compl. ¶¶ 110-15; 212-17).

40. In one such alleged instance, a senior clinical specialist of Medtronic's Cardiac Rhythm Disease Management group performed an in-office interrogation of a patient's device and instructed the "the doctor how it should be billed." (Ex. K, Doe Compl. ¶¶ 110-15).

41. In another such alleged instance, Medtronic hosted a dinner and provided information to physicians as to "how they could obtain additional compensation and enhance their billings if they used this Medtronic cardiac devices exclusively." (Ex. K, Doe Compl. ¶ 215); *see also* (*id.* ¶¶ 212-214, 216-217).

Forney Case

42. Relator Forney last worked for Medtronic in November 2011. (Ex. L, Excerpts of the Deposition of Cathleen Forney ("Forney Tr.") at 50:6-8).

43. She did not believe that the conduct alleged in her complaints violated the law until sometime after she left Medtronic. (Ex. L, Forney Tr. at 126:17 – 130:17).

44. Relator Forney stated at her deposition that she provided approximately 10 or 12 documents to the government in June 2015. (Ex. L, Forney Tr. 153:8 – 154:20). She further stated that to the best of her knowledge all of the documents she provided to the government were cited in her complaints. (*Id.* at 256:4-9).

45. Relator Forney initiated this action by filing her original complaint on November 20, 2015. (ECF No. 1.)

46. Relator filed her first amended complaint on April 3, 2017. (ECF No. 17).

47. Following a dismissal without prejudice, Relator filed her second amended complaint ("SAC") on July 3, 2017. (ECF No. 40).

48. In a Rule 34 request for production of documents, Medtronic asked Relator to produce "All Communications with the Government, including but not limited to all Documents

produced or provided to the Government, in connection with or relating to the Pending Qui Tam Litigation, or its allegations, regardless of date." (Ex. M, Relator's RFP Responses, at 1). Relator objected, asserting various privileges and protections from disclosure. (*Id.* at 2).

49. Medtronic asked Relator in an interrogatory to convey the substance of any communication she had with the government. (Ex. N, Relator's Interrogatory Responses, at 1-2). Relator's counsel objected, again asserting various privileges and protections. (*Id.* at 2).

50. At Relator's deposition, Medtronic again asked Relator to convey the substance of any communications she had with the government. (Ex. L, Forney Tr. 156:2-12). As before, Relator's counsel objected on the grounds that the information was privileged or otherwise protected from disclosure. (*Id.* at 156:13 – 165:6).

51. During her deposition, Relator stated that paragraph 49 of the SAC was based on information contained in Google Calendar records and emails that she accessed after her employment with Medtronic ended. (Ex. L, Forney Tr. 233:4 – 240:4).

52. Relator Forney does not know whether the procedures she alleges in paragraph 49 of her Complaint actually occurred, if any associated patients were Medicare beneficiaries, or if any claims were actually submitted for those procedures and patients. (Ex. L, Forney Tr. 243:13 – 245:18).

Respectfully submitted,

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